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To: Mail Stop Appeal Brief-Patent **From:** Jason D. Voight

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Phone: (571) 272-1000 **Date:** November 1, 2005

Re: Substitute Brief on Appeal **cc:**

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Comments:

In re Application of: **AUWETER, et al.**

Serial No.: **09/929,075**

Filing Date: **August 15, 2001**

Attachments: **REPLY TO OFFICE ACTION MAILED: OCTOBER 14, 2005.**

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In re the application of) Mail Stop: APPEAL BRIEF
AUWETER et al.)
Serial No.: 09/929,075) Confirmation No.: 8919
Filing or 371(c) Date: 08/15/2001) Examiner: Wang, Shengjun
) Art Unit: 1617

For: SOLID PREPARATIONS HAVING A MULTICORE STRUCTURE

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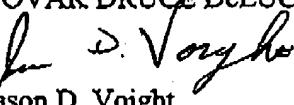
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SUBSTITUTE BRIEF ON APPEAL

This Appeal Brief is from the Examiner's Office Action Mailed on October 14, 2005.
Appeal Brief contained herein is amended for compliance with the requirements of 37 CFR 41.37(c).

Please charge any shortage in fees due in connection with the filing of this paper to Deposit Account 14.1437. Please credit any excess fees to such account.

Respectfully submitted,
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REAL PARTY IN INTEREST

The real party in interest is BASF Aktiengesellschaft, of Ludwigshafen, Germany.
Reel/Frame 012214/0559, recorded on October 1, 2001.

RELATED APPEALS AND INTERFERENCES

To appellants' knowledge and belief, there are no interferences or other appeals which will directly affect or be directly affected by or have a bearing on the Board's decision in this application.

STATUS OF CLAIMS

Claims 1-19 currently are pending in the application. Claims 11-18 have been withdrawn from consideration by the examiner after a restriction requirement was imposed.

STATUS OF AMENDMENTS

The claims have not been amended subsequent to the final office action mailed on October 28, 2003.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to solid preparations of at least two active compounds suitable for the food sector and animal feed sector or for pharmaceutical and cosmetic applications having a multicore structure, in particular carotenoid-containing dry powders, a process for their production and the use of these solid preparations for producing food supplements and as additive to foods, animal feeds, pharmaceutical and cosmetic preparations (see Specification page 1, beginning line 4)

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

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Whether claims 1-10 and 19 are obvious under 35 USC § 103(a) over Akamatsu et al. (US 5,780,056), in view of Khachick (US 5,382,714), Ausick et al. (US 5,648,564) and Horn et al. (US 4,522,743).

ARGUMENT

The following legal authorities are relied on in the following arguments in the order in which they are cited:

In re Rouffet, 149 F.2d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998).

In re Kotzab, 217, F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000).

Claims 1-10 and 19 are rejected under 35 USC § 103(a) as being unpatentable over Akamatsu et al. (US 5,780,056), in view of Khachik (US 5,382,714), Ausich et al. (US 5,648,564) and Horn et al. (US 4,522,743).

The examiner stated that the examiner's conclusion of obviousness is not based upon improper hindsight reasoning because it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure. The examiner believes the cited references teach the usefulness of various carotenoids as food or pharmaceutical ingredients, teach a method of making fine particles of carotenoids, and teach multiple core structures for carotenoids. The examiner believes it is therefore obvious to make a multiple core structure containing various carotenoids by incorporating various final particles of carotenoids into the multiple core structure.

Applicants disagree. It is true that one need not find some teaching, suggestion or motivation to combine the references only explicitly in the references themselves. There are three possible sources for a motivation to combine the references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. " *In re Rouffet*, 149 F.2d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998).

In setting forth the motivation to combine the examiner presumably relies on the knowledge of persons of ordinary skill in the art in stating: "Particularly, the cited references teach the usefulness of various carotenoids as food or pharmaceutical ingredient, teach a method of making

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fine particles of carotenoids, and teach multiple cores structure for carotenoids. It is therefore obvious to make a multiple core structure containing various carotenoids by incorporating various final particles of carotenoids into the multiple core structure." (Office action, 10/28/03, page 3, first paragraph).

Applicants in response point out that each of the multiple core structures shown in the cited art contains the same active ingredient(s). The Examiner is directed to column 3, lines 18-32 of Akamatsu et al. wherein the cited art discloses possible combinations of natural carotenoids for each microcore structure. Further disclosures in Akamatsu et al. favoring Applicants argument that each core structure found in the cited art contains only one category of active ingredient per micro structure can be found in Example 1, of column 7, wherein the cited art lists "palm oil as carotenoid" – no microcore structures containing different chemical compositions are disclosed. Conversely, the present invention however, claims multiple core structures with more than one active ingredient with at least two cores of a multicore structure having a different chemical composition. The examiner dismisses this as an unexpected benefit. However, applicants point to this novel feature of the present invention to show that one would not have been motivated to pick and choose elements from the examiner's cited reference to arrive at the present claims. The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as whole would have suggested to those of ordinary skill in the art." *In re Kotzab*, 217, F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). At the time the present invention was made, multicore structures of different chemical compositions which avoided unwanted interactions were not made. This is also why the examiner's reliance on *In re Kerkhoven* to say that "the claimed invention which is a combination of two known nutritional ingredients sets forth *prima facie* obvious subject matter" is not determinative.

One of the basic requirements of a *prima facie* case of obviousness is there must a reasonable expectation of success. MPEP 2143. The examiner has not set forth why there would be a reasonable expectation of success if only the knowledge of one of ordinary skill in the art at the time of the presently claimed invention is taken into account. Applicants believe there would not be reasonable expectation of success if only based on the knowledge of one of ordinary skill in the art at the time of the presently claimed invention. A feature of the solid preparations of the instant invention is that they prevent or decrease unwanted interactions between the active components

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within the multicore structure. This is accomplished through encapsulation of the individual active compounds. Encapsulation of the individual active compounds also allows for more flexible organization of the production of user-friendly formulations of active-compound containing mixtures.

It would have been well known to one of ordinary skill in the art that carotenoids not only have antioxidant properties but also can act as prooxidants. Prooxidation can cause unwanted interactions among the carotenoids when in close contact. The end result of such activity among carotenoids in close contact is decomposition of the active compounds and thusly, decreased stability of said compounds. The instant invention demonstrates its unexpected results by avoiding decomposition, and the resulting instability, of carotenoids compounds through encapsulation of the individual carotenoids.

Lastly, Khachik et al. and Ausich et al. are only directed to processes for isolation and purification of xanthophyll crystals from natural sources. Neither reference discloses any kind of formulation of xanthophylls. More specifically, neither cited art reference discloses a solid preparation of at least two active compounds suitable for the food sector and animal feed sector, or for pharmaceutical and cosmetic applications, in the form of a multicore structure in which at least two cores of a multicore structure have a different chemical composition.

For the reasons expressed above, it is urged that the prior art references cited by the examiner either singly or in combination fail to anticipate or suggest the present invention as defined by the amended claims. Accordingly, a *prima facie* case of obviousness has not been established by the examiner, and the rejection under 35 USC § 103 should be withdrawn. For the foregoing reasons, it is respectfully submitted that reversal of the examiner's rejection of all claims is in order.

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CLAIMS APPENDIX

1. A solid preparation of at least two active compounds suitable for the food sector and animal feed sector or for pharmaceutical and cosmetic applications in the form of a multicore structure in which at least two cores of a multicore structure have a different chemical composition.
2. A solid preparation as claimed in claim 1, wherein the multicore structure is a particle species having a mean particle size of from 5 to 3000 µm in which the cores are embedded in a matrix.
3. A solid preparation as claimed in claim 1 in which the cores have a mean particle size of from 0.01 to 1.0 µm.
4. A solid preparation as claimed in claim 1, which is a carotenoid-containing dry powder of at least two carotenoids.
5. A carotenoid-containing dry powder as claimed in claim 4, wherein at least two cores comprise one or more different carotenoids.
6. A carotenoid-containing dry powder as claimed in claim 4, wherein at least two cores comprise only one representative of the carotenoid class of substances.
7. A carotenoid-containing dry powder as claimed in claim 4, wherein the carotenoids are a selection from the group of the carotenes and xanthophylls.
8. A carotenoid-containing dry powder as claimed in claim 4, comprising β-carotene, lycopene and lutein.
9. A carotenoid-containing dry powder as claimed in claim 8, comprising 1 part by weight of

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β -carotene, from 0.02 to 20 parts by weight of lycopene and from 0.02 to 20 parts by weight of lutein.

10. A carotenoid-containing dry powder as claimed in claim 4, having a carotenoid content of from 0.1 to 50% by weight, based on the total amount of the dry powder.
11. A process for producing solid preparations defined according to claim 1 by drying an aqueous suspension comprising at least two active compounds which are suitable for the food sector and animal feed sector or for pharmaceutical and cosmetic applications in the form of nanoparticulate particles, which comprises at least two of the nanoparticulate particles having a different chemical composition.
12. A process as claimed in claim 11, wherein the active compounds are at least two carotenoids.
13. A process as claimed in claim 11, wherein at least two of the nanoparticulate particles comprise one or more different carotenoids.
14. A process as claimed in claim 11, wherein at least two of the nanoparticulate particles comprise only one representative of the carotenoid class of substances.
15. A process as claimed in claim 11, wherein the active compounds are present in the form of protective-colloid-stabilized nanoparticulate particles.
16. A process as claimed in claim 11, wherein the nanoparticulate particles have a size of from 0.01 to 1.0 μm .
17. The use of the solid preparation defined according to claim 1 for producing food supplements and as additive to foods, animal feeds, pharmaceutical and cosmetic preparations.

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18. The use as claimed in claim 17 for producing soft gelatin capsules.
19. A food supplement, food, animal feed and pharmaceutical and cosmetic preparation comprising carotenoid-containing preparations defined according to claim 1.

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EVIDENCE APPENDIX

None.

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RELATED PROCEEDINGS APPENDIX

None.